Testimony in Opposition to Prohibition and in Support of Evidence-Based Regulation

Chair and Members of the Committee,

My name is Jessica Gerding. I am a manufacturing consultant and dietary supplement industry professional. I own and operate an ingredient manufacturing facility in Pennsylvania and a supplement manufacturing facility in Florida. My work centers on FDA compliance, quality systems, and botanical ingredient safety.

I am submitting this testimony to address concerns reflected in SB 820 and HB 1523 and to clarify several important regulatory and scientific points regarding kratom.

The New Dietary Ingredient (NDI) Framework Already Governs Kratom

Both bills express concern about safety, lack of FDA approval, and potential risk to public health. It is important to clarify that dietary ingredients are not required to be "FDA approved" like pharmaceutical drugs. They are governed under a different statutory framework.

Under federal law, any dietary ingredient not widely marketed prior to October 15, 1994 must undergo a **New Dietary Ingredient (NDI) notification** before lawful interstate commerce.

The legal standard is not zero risk. The standard is whether the ingredient, under proposed conditions of use, presents a **significant or unreasonable risk of illness or injury**.

An NDI submission requires:

- Botanical identity verification
- Full manufacturing process disclosure
- Detailed ingredient specifications
- Contaminant limits
- Stability data
- Toxicological and safety data.

This is a structured, science-based premarket safety process established by Congress.

A standardized kratom powder, properly manufactured with our assigned NDI number, and our extract manufactured in the United States have undergone this NDI process. They are produced under current Good Manufacturing Practices (cGMP), supported by toxicological review, and manufactured with contaminant testing and alkaloid standardization.

When legislative findings state that Kratom lacks safety review, that is not entirely accurate. The federal safety framework exists and has been utilized.

Distinguishing Between Compliant Manufacturing and Illicit Products

Both SB 820 and HB 1523 cite adverse event concerns, youth exposure, and product

variability. These are legitimate public health considerations. However, they do not distinguish between:

1) Unregulated, imported raw plant material and Regulated plant material that abide by the FDA compliant systems.

2) Unregulated, imported extracts and U.S.-manufactured, standardized extracts produced under FDA-compliant systems.

There is a critical difference.

Domestic cGMP manufacturing requires:

- Supplier qualification programs
- Raw material identity testing
- Heavy metal and microbial analysis
- Batch traceability
- Documented quality control release
- Recall capability

The kratom extract I am referencing is:

- Manufactured in the United States
- Tested for contaminants
- Standardized to defined alkaloid levels
- Supported by toxicology review
- Produced under federal manufacturing law.

If the concern is contamination, adulteration, or variable potency, the solution is to require compliance with these manufacturing standards - not to eliminate the regulated marketplace.

“No FDA Approval” Does Not Mean “No Regulatory Structure”

Language in the bills suggests that because Kratom is not FDA approved as a drug, it lacks oversight.

Dietary supplements are regulated under the Dietary Supplement Health and Education Act (DSHEA), which establishes cGMP manufacturing requirements, labeling standards, adulteration prohibitions, misbranding prohibitions, and FDA enforcement authority.

The correct regulatory question is whether products are being manufactured and marketed in compliance with DSHEA—not whether they have undergone pharmaceutical drug approval.

Conflating these standards risks misunderstanding the regulatory framework Congress intentionally created for botanicals.

Addressing Concerns About Youth Access and Potency

If the legislature's concern is youth access, that is solvable through age restrictions, retail licensing requirements, and enforcement mechanisms.

If the concern is high-potency extracts or synthetic alkaloid manipulation, that is solvable through prohibiting chemically altered alkaloids, setting maximum alkaloid concentration limits, requiring alkaloid disclosure on labeling, and mandating third-party contaminant testing.

These are targeted regulatory tools

A total ban removes compliant operators while leaving illicit markets intact.

Evaluating Risk Under the Proper Legal Standard

The statutory standard for dietary ingredients is whether the product presents a "significant or unreasonable risk" under labeled conditions of use.

No consumer product is risk-free. Many regulated consumable ingredients found in supplements, food, and beverages carry documented risks.

The relevant question is whether a properly manufactured, standardized, U.S.-produced kratom extract—manufactured under cGMP and supported by safety review—presents an unreasonable risk when used as directed.

Policy should be grounded in a comparative risk assessment, not isolated case reports that often involve poly-substance exposure or adulterated products.

Prohibition Reduces Visibility and Oversight

If SB 820 or HB 1523 result in full prohibition, likely outcomes include expansion of online interstate sales, increased importation from unregulated sources, elimination of in-state manufacturing oversight, and reduced product testing transparency.

Prohibition does not eliminate demand. It eliminates regulated supply.

From a manufacturing compliance perspective, the safest marketplace is one where producers are known, facilities are registered, testing is documented, and products are traceable.f

These safeguards disappear when lawful operators are removed.

A Structured Alternative

If the goal is public safety, Maryland could consider:

- Age restrictions
- Mandatory contaminant testing
- Alkaloid content disclosure
- Prohibition of synthetic or chemically altered alkaloids

- Manufacturer and distributor registration
- Enforcement funding

These measures preserve consumer protection while maintaining oversight.

Closing

I do not dismiss safety concerns. The deserve rigorous analysis.

However, the existence of an NDIN for Kratom including a U.S.-manufactured, tested, standardized kratom extract that has undergone the federal New Dietary Ingredient notification process demonstrates that regulation—not prohibition—is the appropriate path.

The federal framework already provides a safety standard, and I work with the ingredients that have met it. We support manufacturing law that provide enforceable quality controls.

If the objective is to reduce risk, policy should strengthen compliance requirements rather than remove regulated participants from the marketplace.

Evidence-based oversight protects consumers. Eliminating regulated manufacturing does not.

Thank you for your consideration.